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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,771	04/02/2004	John J. Koleng	BPH-1	2784

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,771	KOLENG ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-26,29-42,44-47,49,52-54 and 59-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-26,29-42,44-47,49,52-54 and 59-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks, amendments and Request for Continued Examination filed on 5/8/08 are acknowledged.

2. Claims 1, 17, 23, 36, 42, 44 and 52 have been amended.

3. Claims 3-5, 27-28, 43, 48, 50-51 and 55-58 were cancelled.

4. New claims 59-76 were added.

5. Claims 1, 2, 6-26, 29-42, 44-47, 49, 52-54 and 59-76 are included in the prosecution.

Continued Examination under 37 CFR 1.114

6. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/8/08 has been entered.

Response to Arguments

Objection to claims 17 and 42

7. In light of Applicant's amendments of claims 17 and 42, the objection to claims 17 and 42 is withdrawn.

Rejection to claims 1-2, 4-26, 29-42, 44-47, 49-54 and 56-57 under 35 USC § 112

8. In light of Applicant's amendments of claims 1, 23, 36, 44 and 52 (to remove the proviso excluding erythritol), the rejection of claims 1-2, 4-26, 29-42, 44-47, 49-54 and 56-57 under 35 USC § 112, first paragraph is withdrawn.

Rejection of claims 1-2, 4-26, 29-42, 44-47, 49-54, 56-57 under 35 USC § 103(a)

9. Applicant's arguments with respect to the rejection of claims 1-2, 4-26, 29-42, 44-47, 49-54, 56-57 under 35 U.S.C. 103(a) as being unpatentable over Luber et al. (US 2003/0068373) and Applicant's amendment of the claims to include the limitation of the combination of the hydrophilic polymers polyethylene glycol and poloxamer have been fully considered and are found persuasive. The rejection of 1/11/08 is withdrawn.

10. However, upon further consideration, a new ground(s) of rejection is made in view of Puglia et al. (US 4,327,077) and Staniforth (US 2002/0068084).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-2, 6-15, 20-26, 29-41, 44-47, 49, 52-54, 59-60, 62-63, 65-66, 68-69 and 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Puglia et al. (US 4,327,077) in view of Staniforth (US 2002/0068084).

The claimed invention is a rapidly disintegrating and rapidly dissolving solid oral compressed composition consisting essentially of one or more magnesium salt(s), a combination of the hydrophilic polymers polyethylene glycol and poloxamer and one or

more disintegrants selected from the group consisting of crospovidone, low substituted hydroxypropylcellulose, croscarmellose sodium, and sodium starch glycolate. The composition provides a substantially stable dissolution profile when evaluated in vitro according to USP <711> for the one or more magnesium salts when the composition is stored for at least two months at 40°C and 75% relative humidity in a sealed container-enclosure system. The composition excludes microcrystalline cellulose.

Puglia teaches a compressed chewable antacid tablet which has good flexibility, is breakage resistant and disintegrates immediately upon chewing (Abstract). Antacids including magnesium carbonate, magnesium hydroxide and magnesium oxide are disclosed (Col. 4, lines 37-60).

Puglia does not expressly teach the combination of polyethylene glycol and poloxamer.

Staniforth teaches pharmaceutical disintegrants that are incorporated into pharmaceutical solid dosage forms (Page 2, [0002]) such as sodium starch glycolate (Page 2, [0014]) and discloses that by fast disintegration is meant a disintegration time in water at room temperature of less than 2 minutes and preferably less than one minute (Page 3, [0033]). Staniforth also discloses polyethylene glycols (PEG) and poloxamers as hydrophilic surface active materials (Page 6, [0070).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a chewable antacid tablet, as suggested by Puglia, combine it with the disintegrants such as sodium starch glycolate and the hydrophilic

polymers PEG and poloxamer, as suggested by Staniforth, and produce the instant invention.

One of ordinary skill in the art would do this because the use of disintegrants in rapidly disintegrating tablets or solid dosage forms is known in the art, as is the use of hydrophilic polymers PEG and poloxamer (as evidenced by Staniforth). One with ordinary skill in the art would find it obvious to combine the hydrophilic polymers PEG and poloxamer during the process of routine experimentation with a reasonable expectation of success in producing a functional rapidly disintegrating antacid tablet.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 1, 23 and 36, the limitation of a rapidly disintegrating and rapidly dissolving solid oral compressed composition would have been obvious over the tablet that disintegrates immediately upon chewing, as taught by Puglia (Abstract). The limitation of one or more magnesium salts would have been obvious over the magnesium carbonate, magnesium hydroxide and magnesium oxide disclosed by Puglia (Col. 4, lines 37-60). The limitation of a combination of the hydrophilic polymers polyethylene glycol and poloxamer would have been obvious over the polyethylene glycols (PEG) and poloxamers disclosed by Staniforth (Page 6, [0070). The limitation of the disintegrant would have been obvious over the sodium starch glycolate disclosed by

Staniforth (Page 2, [0014]). The limitation of the substantially stable dissolution profile when evaluated in vitro according to USP <711> would have been obvious because one with ordinary skill in the art would measure the dissolution of the antacid tablets during the process of routine experimentation and in order to ensure the stability of the tablets after storage at accelerated stability conditions that are generally used in the art of pharmaceutical product development. The limitation of the composition excluding microcrystalline cellulose would have been obvious over the composition taught by Puglia which does not contain microcrystalline cellulose.

Regarding instant claims 2, 10, 25-26, 37, 38 and 45, the limitation of the magnesium salt would have been obvious over the magnesium carbonate, magnesium hydroxide and magnesium oxide disclosed by Puglia (Col. 4, lines 37-60).

Regarding instant claims 6 and 34, the composition further comprising a coating surrounding the compressed composition would have been obvious over the compressed antacid tablets that may be sealed or spray coated, as taught by Puglia (Col. 5, lines 59-68).

Regarding instant claims 7 and 13, the limitation of a tablet would have been obvious over the compressed tablet taught by Puglia (Abstract).

Regarding instant claims 8, 29, 32, 39-40, 46 and 53, the limitation of dry granulation would have been obvious over the dry blending into the granulation, as taught by Puglia (Col. 3, lines 42-45).

Regarding instant claims 9, 30 and 33, the limitation of direct compression would have been obvious over the direct compaction vehicle under compression, as taught by Puglia (Abstract).

Regarding instant claims 11, 24 and 49, the limitation of the magnesium salt that is the only component present in a therapeutically effective amount would have been obvious over the range of about 10 to about 50% by weight of an antacid material selected from magnesium carbonate, magnesium hydroxide and magnesium oxide, as taught by Puglia (Col. 4, lines 37-60).

Regarding instant claims 12 and 35, the limitation of the composition further comprising a capsule shell within which the compressed composition is enclosed would have been obvious over the granulate that can be admixed with an active ingredient and the mixture then filled into capsules, as taught by Staniforth (Page 8, [0090]).

Regarding instant claim 14, the limitation of the hardness of the tablet would have been obvious over the breakage resistant tablet, as taught by Puglia (Abstract).

Regarding instant claim 15, the limitation of dilute hydrochloric acid as the dissolution medium would have been obvious because one of ordinary skill in the art would follow the method outlined in the USP and use the corresponding dissolution media.

Regarding instant claims 20-22, 31, 47 and 54, the limitations of the compressed composition that contains less than 7.5% water, less than 5.5% water and less than 4% water would have been obvious because one of ordinary skill in the art would follow the

dry blending into the granulation, as taught by Puglia (Col. 3, lines 42-45). One with ordinary skill in the art would minimize the moisture content in the composition in order to enhance the stability of the antacid in the tablet.

Regarding instant claim 41, the limitation of the composition that is prepared by a process that does not include the addition of water would have been obvious because one of ordinary skill in the art would follow the dry blending into the granulation, as taught by Puglia (Col. 3, lines 42-45). One with ordinary skill in the art would minimize the moisture content in the composition in order to enhance the stability of the antacid in the tablet.

Regarding instant claims 44 and 52, the limitation of at least one or more of the following: surfactant, glidant, filler and lubricant would have been obvious over the surfactant (Col. 4, lines 64-18), sweetening agents, lubricants, and bulking agents (Col. 5, lines 43-58) as taught by Puglia. The limitation of a substantially anhydrous process would have been obvious over the dry granulation and direct compression taught by Puglia (Col. 3, lines 42-45 and Abstract).

Regarding instant claims 59, 62, 65, 68, and 71, the disintegration time of 9 to 90 seconds would have been obvious over the compressed chewable antacid tablet which disintegrates immediately upon chewing, as taught by Puglia (Abstract) and the fast disintegration time of less than 2 minutes and preferably less than one minute, as taught by Staniforth (Page 3, [0033]). One with ordinary skill in the art would use the standard method for testing disintegration of the tablet based on the USP, during the process of routine experimentation.

Regarding instant claims 60, 63, 66, 69 and 72, the limitation of at least one or more surfactant, one or more filler and one or more lubricant would have been obvious over the surfactant (Col. 4, lines 64-18), sweetening agents, lubricants, and bulking agents (Col. 5, lines 43-58) as taught by Puglia.

13. Claims 16-19 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Puglia et al. (US 4,327,077) in view of Staniforth (US 2002/0068084) and further in view of Miller et al. (US 5,860,550).

The teachings of Puglia and Staniforth are stated above.

Puglia and Staniforth do not expressly teach a sealed container-enclosure system.

Miller teaches a container that can be used to store tablets or capsules of antacids and also teaches that such medicaments are also safety sealed in an airtight package within the container (Col. 8, lines 10-23). Miller teaches suitable packaging materials including metal, polypropylene or polyethylene (Col. 3, lines 34-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a chewable antacid tablet, as suggested by Puglia, combine it with the disintegrants such as sodium starch glycolate and the hydrophilic polymers PEG and poloxamer, as suggested by Staniforth, further combine it with the storage of antacid tablets in a sealed container, as taught by Miller, and produce the instant invention.

One of ordinary skill in the art would do this in order to enhance the storage stability or shelf life of the antacid tablets which is generally practiced in the art of pharmaceutical product packaging.

Regarding instant claim 16, the sealed container-enclosure system would have been obvious over the medicaments that are safety sealed in an airtight package within a container, as taught by Miller (Col. 8, lines 10-23).

Regarding instant claims 17 and 42, the container material would have been obvious over the metal and polymers taught by Miller (Col. 3, lines 34-46). The tamper evident liner would have been obvious over the transparent or translucent covering portion taught by Miller (Col. 8, lines 18-23).

Regarding instant claim 18, the high density polyethylene and the CRC or non-CRC polypropylene would have been obvious over the polyethylene and polypropylene taught by Miller (Col. 3, lines 34-46). The limitation of sealing using an appropriate torque and an induction sealed aluminum tamper evident liner would have been an obvious variant over the translucent covering because one with ordinary skill in the art would use different liners during the process of routine experimentation.

Regarding instant claim 19, the limitation of direct compression would have been obvious over the direct compaction vehicle under compression, as taught by Puglia (Abstract).

14. Claims 61, 64, 67 and 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Puglia et al. (US 4,327,077) in view of Staniforth (US 2002/0068084) and further in view of Bodor et al. (US 3,891,696).

The teachings of Puglia and Staniforth are stated above.

Puglia and Staniforth do not expressly teach ethylcellulose in the composition.

Bodor teaches that ethylcellulose and lactose are used as binders in a tablet formulation (Col. 23, lines 17-31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a chewable antacid tablet, as suggested by Puglia, combine it with the disintegrants such as sodium starch glycolate and the hydrophilic polymers PEG and poloxamer, as suggested by Staniforth, further combine it with the use of ethylcellulose and lactose as binders in tablets, as taught by Bodor, and produce the instant invention.

One of ordinary skill in the art would do this because ethylcellulose and lactose are known tablet binders (as evidenced by Bodor) and would combine them with the rapidly disintegrating tablet of Puglia.

Regarding instant claims 61, 64, 67 and 73, the limitation of ethylcellulose and lactose would have been obvious over the ethylcellulose and lactose used as binders by Bodor (Col. 23, lines 17-31).

Regarding instant claim 74, the limitation of a rapidly disintegrating and rapidly dissolving solid oral compressed composition would have been obvious over the tablet

that disintegrates immediately upon chewing, as taught by Puglia (Abstract). The limitation of granular magnesium oxide and the magnesium salt which is practically insoluble would have been obvious over the magnesium oxide disclosed by Puglia (Col. 4, lines 37-60). The limitation of a combination of the hydrophilic polymers polyethylene glycol and poloxamer would have been obvious over the polyethylene glycols (PEG) and poloxamers disclosed by Staniforth (Page 6, [0070). The limitation of crospovidone would have been obvious over the disintegrants disclosed by Staniforth (Page 2, [0014]) and by the polyvinylpyrrolidone taught by Bodor (Col. 23, line 30). The limitation of the surfactant would have been obvious over the surfactant taught by Puglia (Col. 4, lines 64-18). The limitation of the glidant would have been obvious over the silica taught by Puglia (Col. 5, line 10). The limitation of ethylcellulose and lactose would have been obvious over the ethylcellulose and lactose used as binders by Bodor (Col. 23, lines 17-31). The limitation of the lubricant would have been obvious over the lubricants taught by Puglia (Col. 5, lines 54-55). The limitation of the substantially stable dissolution profile when evaluated in vitro according to USP <711> would have been obvious because one with ordinary skill in the art would measure the dissolution of the antacid tablets during the process of routine experimentation and in order to ensure the stability of the tablets after storage at accelerated stability conditions that are generally used in the art of pharmaceutical product development. The limitation of a substantially anhydrous process would have been obvious over the dry blending into the granulation, as taught by Puglia (Col. 3, lines 42-45). The limitation of the composition excluding

microcrystalline cellulose would have been obvious over the composition taught by Puglia which does not contain microcrystalline cellulose.

Regarding instant claim 75, the disintegration time of 9 to 90 seconds would have been obvious over the compressed chewable antacid tablet which disintegrates immediately upon chewing, as taught by Puglia (Abstract) and the fast disintegration time of less than 2 minutes and preferably less than one minute, as taught by Staniforth (Page 3, [0033]). One with ordinary skill in the art would use the standard method for testing disintegration of the tablet based on the USP, during the process of routine experimentation.

Regarding instant claim 76, the limitations of polyethylene glycol having a molecular weight of 3000-8000 and poloxamer 188 would have been obvious over the (PEG) and poloxamers disclosed by Staniforth (Page 6, [0070). One with ordinary skill in the art would use different grades of the components during the process of routine experimentation. The recited molecular weight range of the PEG and the particular poloxamer 188 would have been obvious variants unless there is evidence of criticality or unexpected results.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
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